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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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## Complete if Known

Application Number	10/544,145
Filing Date	August 2, 2005
First Named Inventor	Shyam S. Mohapatra
Art Unit	1633
Examiner Name	Scott D. Long
Attorney Docket Number	USF.T192XC1

Sheet 1 of 7

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-2006-0276382-A1	12-07-2006	Mohapatra	All
	U2	US-2002/0044919	04-18-2002	Yu	All
	U3	US-2005/0025742 A1	02-03-2005	Engler <i>et al.</i>	All
	U4	US-2005/0054052 A1	03-10-2005	Carr <i>et al.</i>	All
	U5	US-2005/0054053 A1	03-10-2005	Aguinaldo <i>et al.</i>	All
	U6	US-2005/0084478 A1	04-21-2005	Liu <i>et al.</i>	All
	U7	US-2005/0272850	12-08-2005	Mohapatra	All
	U8	US-4,414,150	11-08-1983	Goeddel	All
	U9	US-4,456,748	06-26-1984	Goeddel	All

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document Country Code <sup>2</sup> - Number <sup>4</sup> - Kind Code <sup>6</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	F1	WO 01/22970 A1	04-05-2001	The Cleveland Clinic Foundation	All	
	F2	WO 2003/074561 A1	09-12-2003	Univ. of South Florida	All	
	F3	WO 03/089003 A1	10-30-2003	Imperial College Innovations Ltd	All	
	F4	WO 2004/074314 A2	09-02-2004	Univ. of South Florida	All	
	F5	WO 2004/022003 A3	03-18-2004	Univ. of South Florida	All	
	F6	WO 2005/094420 A2	10-13-2005	Univ. of South Florida	All	
	F7	WO 90/09780 A1	09-07-1990	Danbiosyst UK Ltd.	All	

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		Number - Kind Code* (if known)			
	U10	US-4,678,751	07-07-1987	Goeddel	All
	U11	US-4,695,623	09-22-1987	Stabinsky	All
	U12	US-4,897,471	01-30-1990	Stabinsky	All
	U13	US-5,766,864	06-16-1998	Uno <i>et al.</i>	All
	U14	US-5,770,191	06-23-1998	Johnson <i>et al.</i>	All
	U15	US-5,831,062	11-03-1998	Taylor	All
	U16	US-5,853,755	12-29-1998	Foldvari	All
	U17	US-6,120,762	09-19-2000	Johnson <i>et al.</i>	All
	U18	US-7,354,908	04-08-2008	Mohapatra <i>et al.</i>	All
	U19	US-7,118,888	10-10-2006	Mohapatra <i>et al.</i>	All

**FOREIGN PATENT DOCUMENTS**

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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	F8	WO 98/02457 A1	01-22-1998	Connaught Lab. Lmtd.	All	
	F9					
	F10					
	F11					
	F12					
	F13					

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			Filing Date	August 2, 2005	
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			Examiner Name	Scott D. Long	
			Attorney Docket Number	USF.T192XC1	
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## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R1	AGNIHOTRI, S.A. <i>et al.</i> "Recent advances on chitosan-based micro- and nanoparticles in drug delivery" <i>J Control Release</i> , 2004 Nov 5, 100(1):5-28.	
	R2	AGRAWAL, S. and KANDIMALLA, E.R. "Antisense therapeutics: is it as simple as complementary base recognition?" <i>Mol. Med. Today</i> , 2000, 6:72-81	
	R3	ANTONIOU, K.M. <i>et al.</i> "Interferons and their application in the diseases of the lung" <i>Chest</i> , 2003, 123:209-216.	
	R4	ARAL, C. and AKBUGA, J. "Preparation and in vitro transfection efficiency of chitosan microspheres containing plasmid DNA-poly(L-lysine) complexes" <i>J Pharm Pharm Sci.</i> , 2003 Sep-Dec, pp. 321-6, Vol. 6, No. 3.	
	R5	BENAVENTE, J. <i>et al.</i> "Indiscriminate Degradation of RNAs in Interferon-Treated, Vaccinia Virus-Infected Mouse L Cells" <i>J. Virology</i> , 1984, pp. 866-871, Vol. 51, No. 3.	
	R6	BISBAL, C. <i>et al.</i> "Cloning and Characterization of a RNase L Inhibitor" <i>J. Biol. Chem.</i> , 1995, pp. 13308-13317, Vol. 270, No. 22.	
	R7	BRANCH, A. "A good antisense molecule is hard to find" <i>Trends in Biochem. Sci.</i> , 1998, 23:45-50.	
	R8	CEVC, G. <i>et al.</i> "Ultraflexible vesicles, transfersomes, have an extremely low pore penetration resistance and transport therapeutic amounts of insulin across the intact mammalian skin" <i>Biochim. Biophys. Acta</i> , 1998, 1368:201-215.	
	R9	CHEN, J.H. "Application of cationic polymer vector for gene delivery systems" <i>Yao Xue Xue Bao</i> , 2003 Apr, 38(4):316-20, abstract.	
	R10	CHEN, W.R. "Enhancement of laser cancer treatment by a chitosan-derived immunoadjuvant" <i>Photochem Photobiol.</i> , 2005 Jan-Feb, 81(1):190-5, abstract.	
	R11	CHIRILA, T. <i>et al.</i> "The use of synthetic polymers for delivery of therapeutic antisense oligodeoxynucleotides" <i>Biomaterials</i> , 2002, 23:321-342.	
	R12	COCCIA, E.M. <i>et al.</i> "Cells resistant to interferon- $\beta$ respond to interferon- $\gamma$ via the Stat1-IRF-1 pathway" <i>Virology</i> , 1995, 211:113-122.	
	R13	COHEN, A.D. <i>et al.</i> "Modulating the immune response to genetic immunization" <i>FASEB J.</i> , 1998, pp. 1611-1626, Vol. 12.	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			<b>Application Number</b>	10/544,145
(use as many sheets as necessary)			<b>Filing Date</b>	August 2, 2005
			<b>First Named Inventor</b>	Shyam S. Mohapatra
			<b>Group Art Unit</b>	1633
			<b>Examiner Name</b>	Scott D. Long
			<b>Attorney Docket Number</b>	USF.T192XC1
Sheet	4	of	7	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	R14	COLLIOTT, P.L. <i>et al.</i> "Production of infectious human respiratory syncytial virus from cloned cDNA confirms an essential role for the transcription elongation factor from the 5' proximal open reading frame of the M2 mRNA in gene expression and provides a capability for vaccine development" <i>PNAS USA</i> , 1995, 92:11563-11567.		
	R15	CROOKE, S.T. "Basic principles of antisense therapeutics" in <i>Antisense Research and Application</i> , Ed. by Crooke, S.T., 1998, Chapter 1, pages 1-50.		
	R16	DOBSON, J. "Gene therapy progress and prospects: magnetic nanoparticle-based gene delivery" <i>Gene Therapy</i> , 2006, 13:283-287.		
	R17	DOMACHOWSKIE, J. and ROSENBERG, H. "Respiratory syncytial virus infection: Immune response, immunopathogenesis, and treatment" <i>Clin. Microbiol. Rev.</i> , 1999, 12:298-309.		
	R18	ELLIOTT, G. and O'HARE, P. "Intercellular trafficking and protein delivery by a herpesvirus structural protein" <i>Cell</i> , 1997, 88:223-233.		
	R19	ENGBLEBIENNE, P. "RNase L in health and disease: What did we learn recently?" <i>J. Chronic Fatigue Syndrome</i> , 2003, 11(2):97-109.		
	R20	FOLDVARI, M. and MORELAND, A. "Clinical observations with topical liposome-encapsulated interferon alpha for the treatment of genital papillomavirus infections" <i>J. Liposome Res.</i> , 1997, 7:115-126.		
	R21	FOLDVARI, M. <i>et al.</i> "Liposome encapsulated prostaglandin E <sub>1</sub> in erectile dysfunction: Correlation between in vitro delivery through foreskin and efficacy in patients" <i>Urology</i> , 1998, 52(5):838-843.		
	R22	GOSWAMI, B.B. and O.K. SHARMA "Degradation of rRNA in Interferon-treated Vaccinia Virus-infected Cells" <i>J. Biol. Chem.</i> , 1984, 259(3):1371-1374.		
	R23	GUANG LIU, W. and DE YAO, K. "Chitosan and its derivatives—a promising non-viral vector for gene transfection" <i>J Control Release</i> , 2002 Sep 18, 83(1):1-11.		
	R24	GUTTERMAN, J.U. "Cytokine therapeutics: Lessons from interferon $\alpha$ " <i>Proc. Natl. Acad. Sci. USA</i> , 1994, 91:1198-1205.		
	R25	HELLERMANN, G.R. and MOHAPATRA, S.S. "Genetic therapy: on the brink of a new future" <i>Gen Vacc &amp; Ther</i> , 2003, 1:1.		
	R26	JEONG, H.J. <i>et al.</i> "Nitric oxide production by high molecular weight water-soluble chitosan via nuclear factor-kappaB activation" <i>Int J Immunopharmacol.</i> , 2000 Nov, 22(11):923-33.		

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	R27	JUMMA, M. <i>et al.</i> "Physicochemical properties of chitosan-lipid emulsions and their stability during the autoclaving process." <i>Int'l J Pharm.</i> , 1999, 183:175-184.		
	R28	KUMAR, MNV R. <i>et al.</i> "Nanoparticle-mediated gene delivery: state of the art" <i>Expert Opin. Biol. Ther.</i> , 2004, 4(8):1213-1224.		
	R29	KIM, T.H. <i>et al.</i> "Efficient gene delivery by urocanic acid-modified chitosan" <i>J Control Release</i> , 2003 Dec 12, 93(3):389-402.		
	R30	KIM, T.H. <i>et al.</i> "Galactosylated chitosan/DNA nanoparticles prepared using water-soluble chitosan as a gene carrier" <i>Biomaterials</i> , 2004 Aug, 25(17):3783-92.		
	R31	KINSEY, B. <i>et al.</i> "Non-viral gene delivery to the lungs" <i>Current Gene Therapy</i> , 2005, 5:181-194.		
	R32	KOPING-HOGGARD, M. <i>et al.</i> "Improved chitosan-mediated gene delivery based on easily dissociated chitosan polyplexes of highly defined chitosan oligomers" <i>Gene Ther.</i> , 2004 Oct, 11(19):1441-52.		
	R33	KUMAR, M. <i>et al.</i> "Chitosan IFN- $\gamma$ -pDNA nanoparticle (CIN) therapy for allergic asthma" <i>Genet Vacc &amp; Ther</i> , 2003, 1(1):3.		
	R34	LEONG, K.W. <i>et al.</i> "DNA-polycation nanospheres as non-viral gene delivery vehicles" <i>J. Controlled Release</i> , 1998, 53:183-193.		
	R35	LI, X-L. <i>et al.</i> "RNase L Mediates the Antiviral Effect of Interferon through a Selective Reduction in Viral RNA during Encephalomyocarditis Virus Infection" <i>J. Virology</i> , 1998, 72(4):2752-2759.		
	R36	MANSOURI, S. <i>et al.</i> "Chitosan-DNA nanoparticles as non-viral vectors in gene therapy: strategies to improve transfection efficacy" <i>Eur J Pharm Biopharm.</i> , 2004 Jan, 57(1):1-8.		
	R37	MAO, H-Q. <i>et al.</i> "Chitosan-DNA nanoparticles as gene carriers: synthesis, characterization and transfection efficiency" <i>J. Controlled Release</i> , 2001, 70(3):399-421.		
	R38	MATSUSE, H. <i>et al.</i> "Differential cytokine mRNA expression in <i>Dermatophagoides farinae</i> allergen-sensitized and respiratory syncytial virus-infected mice" <i>Microbes and Infect.</i> , 2000, 2:753-759.		
	R39	MOHAPATRA, S.S. "Mucosal gene expression vaccine: a novel vaccine strategy for respiratory syncytial virus" <i>Pediatr. Infect. Dis. J.</i> , 2003, 22(2 Suppl):S100-S104.		

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	R40	MOHAPATRA, S. Poster materials presented at International RSV Conference on June 22, 2002, Washington, D.C. (9 pages, including abstract and Figures 1-4 with captions).	
	R41	MONTGOMERY, D. et al. "DNA vaccines" <i>Pharmacol. Ther.</i> , 1997, 74:195-205.	
	R42	OPALINSKA, J.B. and GEWIRTZ, A. "Nucleic-acid therapeutics: Basic principles and recent applications" <i>Nature Rev.</i> , 2002, 1:503-514.	
	R43	OPDENAKKER, G. et al. "Interaction of interferon with other cytokines" <i>Experientia</i> , 1989, 45:513-520.	
	R44	PARK, S.-Y. et al. "IFN- $\gamma$ enhances TRAIL-induced apoptosis through IRF-1" <i>Eur. J. Biochem.</i> , 2004, 271(21):4222-4228.	
	R45	PAYNE, L. et al. "Particle-mediated DNA vaccination of mice, monkeys and men: Looking beyond the dogma" <i>Curr. Opin. Mol. Therapeut.</i> , 2002, 4:459-466.	
	R46	PENG, J. et al. "Influence of anions on the formation and properties of chitosan-DNA nanoparticles" <i>J Nanosci Nanotechnol.</i> , 2005 May, 5(5):713-7, abstract.	
	R47	PERACCHI, A. "Prospects for antiviral ribozymes and deoxyribozymes" <i>Rev. Med. Virol.</i> , 2004, 14:47-64.	
	R48	POOGA, M. et al. "Cell penetration by transportan" <i>The FASEB J.</i> , 1998, 12:67-77.	
	R49	POUTON, C. and SEYMOUR, L. "Key issues in non-viral gene delivery" <i>Adv. Drug Deliv. Rev.</i> , 2001, 46:187-203.	
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	R51	READ, M. et al. "Barriers to gene delivery using synthetic vectors" <i>Adv. in Genetics</i> , 2005, 53:19-46.	
	R52	REIS, L.F.L. et al. "Critical role of a common transcription factor, IRF-1, in the regulation of IFN- $\beta$ and IFN-inducible genes" <i>The EMBO J.</i> , 1992, 11(1):185-193.	

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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## Complete if Known

Application Number	10/544,145
Filing Date	August 2, 2005
First Named Inventor	Shyam S. Mohapatra
Group Art Unit	1633
Examiner Name	Scott D. Long
Attorney Docket Number	USF.T192XC1

Sheet	7	of	7
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## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article. (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R53	ROY, K. <i>et al.</i> "Oral gene delivery with chitosan-DNA nanoparticles generates immunologic protection in a murine model of peanut allergy" <i>Nat Med</i> , 1999, 5:387-391.	
	R54	SETHI, S.K. <i>et al.</i> "Interferon-gamma (IFN-γ) down-regulates the rhinovirus-induced expression of intercellular adhesion molecule-1 (ICAM-1) on human airway epithelial cells" <i>Clin. Exp. Immunol.</i> , 1997, 110:362-369.	
	R55	SHIBATA, Y. <i>et al.</i> "Alveolar macrophage priming by intravenous administration of chitin particles, polymers of N-acetyl-D-glucosamine, in mice" <i>Infect Immun.</i> , 1997 May, 65(5):1734-41.	
	R56	SHORT, S.M. <i>et al.</i> "Percutaneous absorption of biologically-active interferon-gamma in a human skin graft-nude mouse model" <i>Pharm. Res.</i> , 1996, 13:1020-1027.	
	R57	SILVERMAN, R.H. "Implications for RNase L in prostate cancer biology" <i>Biochemistry</i> , 2003, 42(7):1805-1812.	
	R58	SIMMONS, C.P. <i>et al.</i> "Mucosal delivery of a respiratory syncytial virus CTL peptide with enterotoxin-based adjuvants elicits protective, immunopathogenic, and immunoregulatory antiviral CD8 <sup>+</sup> T cell responses" <i>J. Immunol.</i> , 2001, 166:1105-1113.	
	R59	WAN, L.Q. <i>et al.</i> "Study of the uptake of chitosan oligosaccharide nanoparticles by A549 cells" <i>Yao Xue Xue Bao</i> , 2004 Mar, 39(3):227-31, abstract.	
	R60	WRIGHT, P. <i>et al.</i> "Evaluation of a live, cold-passaged, temperature-sensitive, respiratory syncytial virus vaccine candidate in infancy" <i>J. Infect. Dis.</i> , 2000, 182:1331-1342.	
	R61	XIU, Q. <i>et al.</i> "Effect of intratracheally administered IL-12 recombinant adenovirus on ovalbumin induced bronchial hyperresponsiveness in mouse model" <i>Chin. J. Tuberc. Respir. Dis.</i> , 2001, 24:298-301.	
	R62	YOO, H.S. <i>et al.</i> "Self-assembled nanoparticles containing hydrophobically modified glycol chitosan for gene delivery" <i>J Control Release</i> , 2005 Mar 2, 103(1):235-43; Epub 2005 Jan 15.	
	R63	ZHU, Z. <i>et al.</i> "Acidic mammalian chitinase in asthmatic Th2 inflammation and IL-13 pathway activation" <i>Science</i> , 2004, 304:1678-1682.	
	R64	ZOON, K.C. "Human interferons: Structure and function" <i>Interferon</i> , 1987, 9:1-12.	
	R65	Copy of European Patent Office Summons to attend oral proceedings pursuant to Rule 115(1) EPC, dated October 22, 2008, for corresponding EPO application no. 04711150.5.	

Examiner Signature	Date Considered
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